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09/807,007	07/09/2001	Peter G. Zaphiropoulos	2921-0130P	8337

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/16/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/807,007

Applicant(s)

ZAPHIROPOULOS ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-17 and 44-47 is/are pending in the application.
- 4a) Of the above claim(s) 1,6-10,13,14,16 and 17 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44 and 47 is/are allowed.
- 6) ☒ Claim(s) 2,4,5,11,12,15,45 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Claims 18-43 were added in the amendment filed 2/19/03 and were canceled in the amendment filed 4/14/03. Claim 3 has been canceled and claims 44-47 have been added and claims 2, 4-5, 15 have been amended.
2. Claims 1, 6-10, 13-14, 16-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper No. 9.
3. Claims 2, 4, 5, 11, 12, 15, 44-47 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
5. The following Office Action contains some NEW GROUNDS of rejection.

### ***Rejections Withdrawn***

6. The rejection of claims 2-4, 5, 11-12, and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.
7. The rejection of claims 2, 5, 11-12 under 35 U.S.C. 102(b) as being anticipated by Motoyama et al (Nature Genetics 18:104-106, 2/98, IDS #11/2) is withdrawn in view of the amendment to the claims.

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8. The rejection of claims 2, 5, 11-12 under 35 U.S.C. 103(a) as being unpatentable over Motoyama et al (Nature Genetics 18:104-106, 2/98, IDS 1 ½) is withdrawn in view of the amendments to the claims.

***Response to Arguments***

9. The rejection of claim 15 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

The response filed 4/14/03 has been carefully considered but is deemed not to be persuasive. The response states claim 15 requires the presence of a nucleic acid according to claims 2 or 4 and the nucleic acids are specifically defined. In response to this argument, the claim still encompasses a genus of nucleic acids (for example claim 4) but the specification only teaches SEQ ID NO:5. Therefore, it is reasonable to conclude that the claim encompasses subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. The rejection of claim 2, 4, 5, 11-12, 15, and newly added claims 45 and 47 under 35 U.S.C. 112, first paragraph is maintained.

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The response filed 4/14/03 has been carefully considered but is deemed not to be persuasive. The response that claim 2 has been amended to remove "variant" and "analog" and claim 4 recites specific hybridization conditions coupled to the structure recited in claim 2 (see page 7 of response). In response to this argument, while claim 2 does recite a structure of SEQ ID NO:1, claim 4 only requires a nucleic acid that hybridizes with the DNA of claim 2 (which claim 4 does not require the DNA to encode SEQ ID NO:1) and as such the claims are still broadly drawn to any nucleic acid that hybridize to a DNA encoding SEQ ID NO:1 or SEQ ID NO:5 (claim 45 and 46). Again the claims encompass nucleic acids that would not function as SEQ ID NO:1, as well as nucleic acids for the detection of any PTCH2 gene wherein it is not clear what structural and functional characteristics are encompassed by a PTCH2 gene that encodes a PTCH2 protein. As stated in the rejection protein chemistry is probably one of the most unpredictable areas of biotechnology. As such one skill in the art would not know how to use just any DNA that hybridizes to a DNA encoding SEQ ID NO:1 or DNA of SEQ ID NO:5. Under the recited hybridization conditions, a multitude of DNA's would hybridize because the conditions are at low temperature and no time is indicated or washing conditions indicated.

Thus, one skilled in the art would be forced into undue experimentation in order to practice the broadly claimed invention.

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11. The rejection of claim 4, and newly added claims 45 and 47 under 35 U.S.C. 102(b) as being anticipated by Motoyama et al (Nature Genetics 18:104-106, 2/98, IDS #11/2) is maintained.

The response filed 4/14/03 has been carefully considered but is deemed not to be persuasive. The response states that Motoyama deals with the mouse sequence which is different from the human and the gene encoding the human patched2 protein was shown for the first time according to the present invention and Motoyama only mentions the role of patched in carcinoma not patched2 (see pages 7-8 of response). In response to this argument, claims 4, 19 and 21 do not require the nucleic acid encode the human protein of SEQ ID NO:1 and as such the art reads on the claims and the DNA of Motoyama would hybridize under the recited conditions.

12. The rejection of claims 2, 4, 5, 11-12 and newly added claims 45 and 47 under 35 U.S.C. 102(e) as being anticipated by Sauvage et al (U.S. Patent 6,348,575, with priority to 4/15/98) is maintained.

The response filed 4/14/03 has been carefully considered but is deemed not to be persuasive. The response states Sauvage fails to suggest or disclose the presently claimed sequences (see page 8 of response). In response to this argument, claim 2 recites a nucleic acid that encodes a human protein that is essentially comprised of SEQ ID NO:1. The nucleic acid of Sauvage does encode a human protein that is essentially comprised of SEQ ID NO:1 and as such the art reads on the claims. The phrase "essentially comprised" is open language and thus SEQ ID NO:1 can have

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additional amino acids. In addition the nucleic acid of Sauvage would hybridize to SEQ ID NO:5 under the recited conditions.

13. The rejection of claim 4 and newly submitted claims 45 and 47 under 35 U.S.C. 102(b) as being anticipated by the Boehringer Mannheim 1991 catalog is maintained.

The response filed 4/14/03 has been carefully considered but is deemed not to be persuasive. The response states that there is no indication that the random primers would hybridize to a nucleic acid encoding SEQ ID NO:1 (see page 9 of response). In response to this argument, it is inherent that the primers would hybridize to a sequence in the nucleic acid that encodes SEQ ID NO:1 under the recited conditions.

14. The rejection of claims 4, and 15 under 35 U.S.C. 103(a) as being unpatentable over Motoyama et al (Nature Genetics 18:104-106, 2/98, IDS 1 ½) is maintained.

The response filed 4/14/03 has been carefully considered but is deemed not to be persuasive. The response states there is no motivation in Motoyama to arrive at the currently claimed subject matter (see page 9 of response). In response to this argument, no positive recitation of the kit ingredients/elements distinguishes the claim over the references. Therefore, the references read on the claimed kit. Further, it is a well-known convention in the art to place the recited elements in a kit comprising a container for the advantages of convenience and economy.

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Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

15. The rejection of claims 2, 4, 5, 11-12, 15, and newly added claims 45 and 47 under 35 U.S.C. 103(a) as being unpatentable over Sauvage et al (U.S. Patent 6,348,575, with priority to 4/15/98) is maintained.

The response filed 4/14/03 has been carefully considered but is deemed not to be persuasive. The response states there is no motivation in Sauvage to arrive at the currently claimed subject matter (see page 9 of response). In response to this argument, no positive recitation of the kit ingredients/elements distinguishes the claim over the references. Therefore, the references read on the claimed kit. Further, it is a well-known convention in the art to place the recited elements in a kit comprising a container for the advantages of convenience and economy.

Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

### ***Conclusion***

16. Claims 44 and 46 are in condition for allowance. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,309,879.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

19. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in

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Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, consisting of several overlapping, slanted strokes that form a stylized representation of the name 'Larry R. Helms'.